OCT 27 2005

K052721

EXHIBIT 2

Mikasa X-Ray Co., LTD. (Manufacturer) 13-2, Hongo 3-chome Bunkyo-Ku, Tokyo 113-0033 Japan Tel 81-3-3813-3911 Fax 81-3-3813-4420	MinXray, Inc (Initial Distributor) 3611 Commercial Ave. Northbrook, IL 60062 Tel 847-564-0323 Fax 847-564-9040 Contact: Keith Kretchmer

September 24, 2005

510(k) Summary

1. **Identification of the Device:**
   Proprietary-Trade Name: *MinXray HF100H+*™ High Frequency Diagnostic X-Ray Unit"
   Classification Name: Mobile X-ray system, Product Code 90 IZL
   Common/Usual Name: Portable general purpose diagnostic X-ray Unit.

2. **Equivalent legally marketed devices** This product is similar in function to the MinXray HF100H K973712 and MinXray HF120/60H PowerPlus™ K040046

3. **Indications for Use (intended use)** The *MinXray HF100H+*™ is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.

4. **Description of the Device:** *MinXray HF100H+*™ is a portable unit which operates from 120 V 50-60~ AC. The unit utilizes a newly designed high frequency inverter and can be mounted to a tripod or support arm. The usual safety precautions regarding the use of x-rays must be observed by the operator.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate device.

6. **Substantial Equivalence Chart,** *MinXray MinXray HF100H+*™

Characteristic	Minxray HF100H (K973712)	MinXray HF120/60H (K040046)	MinXray HF100H+ (Modified device
Intended Use :	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for talking diagnostic x-rays.	SAME as HF100H	SAME as HF100H
Size/weight	406 x 222 x 241 mm 18.6kgs	413 x 224 x 29.2 mm 17.51 kgs	SAME as HF100H
Energy Source	100-140V 50-60 Hz AC3.0kVA	100-260V 50-60Hz AC3.5kVA	SAME as HF100H

Characteristic	Minxray HF100H (K973712)	MinXray HF120/60H (K040046)	MinXray HF100H+ (Modified device
Mounting method	Unit is usually mounted to a MinXray XGS MKIII Portable Stand	SAME as HF100H	SAME as HF100H
User Interface	Up-Down pushbuttons for kVp selections and exposure time selections with LED indictors	Up-Down pushbuttons for kVp selections and exposure time selections with LED indictors and mAs indicators	SAME as HF120/60H
Exposure switch	Dual-stage, deadman type	SAME as HF100H	SAME as HF100H
Controls	Analog/digital, no software	Software based, 2 CPUs.	SAME as HF120/60H
Construction	Monobloc HF a generator, Medical full bridge inverter system	SAME as HF100H	SAME as HF100H
High Voltage Energy Source	High frequency (60kHz) inverter	High frequency (40kHz) inverter	SAME as HF100H
Line Voltage adjustment	Automatic, dynamic	SAME as HF100H	SAME as HF100H
Exposure times	199(in 0.01 sec. Steps) 0.08 - 4.00 sec	0.01-0.2 sec(in 0.01 sec. Steps) 0.2-0.4 sec(in 0.02 sec. Steps) 0.4-1.0 sec(in 0.05 sec. Steps) 1.0-5.0 sec(in 0.1 sec. Steps)	0.03-0.2 sec(in 0.01 sec. Steps) 0.2-0.4 sec(in 0.02 sec. Steps) 0.4-1.0 sec(in 0.05 sec. Steps) 1.0-4.0 sec(in 0.1 sec. Steps)
Tube potential (kV)	40 - 100kV 2kVstep	40 - 120kV 2kVstep	SAME as HF100H
kV steps	31(2kV-step)	41(2kV-step)	31(2kV-step)
Tube current (mA)	20mA	60/42mA(40-50kV) 50/35mA(52-60kV) 45/31.5mA(62-70kV) 38/26.6mA(72-80kV) 33/23.1 mA(82-90kV) 30/21 mA(92-100kV) 20/14mA(102-120kV)	30mA(40-60kV) 25mA(62-80kV) 20mA(82-100kV)
mA steps	Constant	0.01-0.1 sec. (Hi mA) 0.11-5.0 sec. (Low mA)	SAME as HF100H
X-ray tube	Toshiba D-124S	SXR-130 Focus x 1.2	SAME as HF100H
Anode heat Storage	20,000HU	65,000HU	SAME as HF100H
Focal Spot Size	1.2 mm	SAME as HF100H	SAME as HF100H
mAs	1.6-80mAs	0.6-202mAs	0.6-120mAs
Total filtration	4.2mm AL equivalent	3.2mm AL equivalent	SAME as HF120/60H

Characteristic	Minxray HF100H (K973712)	MinXray HF120/60H (K040046)	MinXray HF100H+ (Modified device
Collimator	Advantech R72 Continuously adjustable light beam type with central x-ray indicator	SAME as HF100H	SAME as HF100H
Source to Skin Distance (SSD)	300 mm	SAME as HF100H	SAME as HF100H
Performance Standard	21CFR 1020.30	SAME as HF100H	SAME as HF100H
Electrical safety	UL2601, IEC60601-1	SAME Plus UL listed	SAME as HF100/60H

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of MinXray that the *MinXray HF100H+*™ is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device. Safety is further assured by Underwriters Laboratories testing and listing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2005

MinXray, Inc.
% Mr. Daniel Kamm, P.E.
Regulatory Engineer
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K052721
Trade/Device Name: MinXray HF100H+™
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: IZL
Dated: September 24, 2005
Received: September 30, 2005

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052721

Device Name: MinXray HF100H+™

Indications For Use:

The MinXray HF100H+™ is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052721